

Environmental Protection Agency

§ 158.2204

obtained from the Agency's Web site at <http://www.epa.gov/pesticides>.

§ 158.2203 Definitions.

The following terms are defined for the purposes of this subpart:

Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment.

Fungicide means a substance, or mixture of substances, that destroys fungi (including yeasts) and fungal spores pathogenic to man or other animals in the inanimate environment.

Microbiological water purifier means any unit, water treatment product or system that removes, kills or inactivates all types of disease-causing microorganisms from the water, including bacteria, viruses and protozoan cysts, so as to render the treated water safe for drinking.

Sanitizer means a substance, or mixture of substances, that reduces the bacteria population in the inanimate environment by significant numbers, but does not destroy or eliminate all bacteria. Sanitizers meeting Public Health Ordinances are generally used on food contact surfaces and are termed sanitizing rinses.

Sterilant means a substance, or mixture of substances, that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses.

Tuberculocide means a substance, or mixture of substances, that destroys or irreversibly inactivates tubercle bacilli in the inanimate environment.

Virucide means a substance, or mixture of substances, that destroys or irreversibly inactivates viruses in the inanimate environment.

§ 158.2204 Public health and nonpublic health claims.

(a) *Public health claim*. An antimicrobial pesticide is considered to make a public health claim if the pesticide product bears a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user,

including but not limited to, microorganisms infectious to man in any area of the inanimate environment. A product makes a public health claim if one or more of the following apply:

(1) A claim is made for control of specific microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include, but are not limited to: *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *Escherichia coli* (*E. coli*), *human immunodeficiency virus* (*HIV*), *Streptococcus*, and *Staphylococcus aureus*. Claims for control of microorganisms infectious or pathogenic only to animals (such as canine distemper virus or hog cholera virus) are not considered public health claims.

(2) A claim is made for the pesticide product as a sterilant, disinfectant, virucide, sanitizer, or tuberculocide against microorganisms that are infectious or pathogenic to man.

(3) A claim is made for the pesticide product as a fungicide against fungi infectious or pathogenic to man, or the product does not clearly state that it is intended for use only against nonpublic health fungi.

(4) A claim is made for the pesticide product as a microbiological water purifier or microbial purification system.

(5) A non-specific claim is made that the pesticide product will beneficially impact or affect public health at the site of use or in the environment in which it is applied, and:

(i) The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health microorganism and there is no other functional purpose for the ingredient in the product; or

(ii) The pesticide product is similar in composition to a registered pesticide product that makes antimicrobial public health claims.

(b) *Nonpublic health claim*. An antimicrobial pesticide is considered to make a nonpublic health claim if the pesticide product bears a claim to control microorganisms of economic or aesthetic significance, where the presence of the microorganism would not normally lead to infection or disease in humans. Examples of nonpublic health

claims include, but are not limited to: Algaecides, slimicides, preservatives and products for which a pesticidal claim with respect to odor sources is made.

§ 158.2210 Product chemistry.

The product chemistry data requirements of subpart D of this part apply to antimicrobial products covered by this subpart.

§ 158.2220 Product performance.

(a) *General*—(1) *Product performance requirement for all antimicrobial pesticides.* Each applicant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(2) *Product performance data for each product that bears a public health claim.* Each product that bears a public health claim, as described in § 158.2204(a), must be supported by product performance data, as listed in the table in paragraph (c) of this section.

Product performance data must be submitted with any application for registration or amended registration.

(3) *Product performance data for each product that bears a nonpublic health claim.* Each product that bears a nonpublic health claim, as described in § 158.2204(b), must be supported by product performance data. Each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(4) *Determination of data requirements.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (c) of this section to determine the product performance data requirements for antimicrobial pesticide products.

(b) *Key.* R = Required; EP = End-use product.

(c) *Antimicrobial product performance data requirements table.* The following table shows the data requirements for antimicrobial product performance.

TABLE—ANTIMICROBIAL PRODUCT PERFORMANCE DATA REQUIREMENTS

| Guideline No. | Data requirement | All use patterns | Test substance |
|----------------|---|------------------|----------------|
| 810.2100 | Sterilants—Efficacy Data Recommendations | R | EP |
| 810.2200 | Disinfectants for Use on Hard Surfaces—Efficacy Data Recommendations. | R | EP |
| 810.2300 | Sanitizers for Use on Hard Surfaces—Efficacy Data Recommendations. | R | EP |
| 810.2400 | Disinfectants and Sanitizers for Use on Fabrics and Textiles—Efficacy Data Recommendations. | R | EP |
| 810.2500 | Air Sanitizers—Efficacy Data Recommendations. | R | EP |
| 810.2600 | Disinfectants for Use in Water—Efficacy Data Recommendations. | R | EP |

§ 158.2230 Toxicology.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (g) of this section to determine the toxicology data requirements for an antimicrobial pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions are listed in paragraph (h) of this section.

(b) *Uses.* The applicant for registration must first determine whether the

use is likely to result in pesticide residues in food or water and therefore consult the “Food Use” columns of the table in paragraph (g) of this section. Generally, if the residues of the antimicrobial result from an application to a surface or if incorporated into a material that may come into contact with food or feed, and residues may be expected to transfer to such food or feed, then the “Indirect Food Uses” columns is to be consulted.